From: Dempsey, Donald A. </O=CVSCAREMARK/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=U037682>
To: Sargent, Michael D.; Davis, Thomas G.; Harrington, Nicole J.
Sent: 5/26/2017 11:04:11 AM
Subject: FW: UPDATED Pre-Read for June 1 Executive Committee Meeting--Potential Positions of NACDS to Address Opioid Abuse
Importance: High
Attachments: Policy Council Recs to the EC on Opioid.pdf

FYI

From: Koerner, Kimberly A.
Sent: Friday, May 26, 2017 11:02 AM
To: Schulman, Melissa A.
Cc: Dempsey, Donald A.; Sargent, Michael D.
Subject: FW: UPDATED Pre-Read for June 1 Executive Committee Meeting--Potential Positions of NACDS to Address Opioid Abuse

FYI

Thank you,
Kimberly

Kimberly A. Koerner | Administrative Assistant, CVS Health
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From: Steve Anderson [mailto:SAnderson@NACDS.org]
Sent: Friday, May 26, 2017 10:33 AM
To: Alex.gourlay@walgreens.com; craigpainter@kinneydrugs.com; Foulkes, Helena B.; jstandley@riteaid.com; mgriffin@lewisdrug.com; mark.panzer@albertsons.com; otto.martin@heb.com; redeker@hy-vee.com; rnarveson@thriftywhite.com
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Subject: UPDATED Pre-Read for June 1 Executive Committee Meeting--Potential Positions of NACDS to Address Opioid Abuse

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TO: NACDS Executive Committee

FROM: Steve Anderson

SUBJECT: **UPDATED** Pre-Read for June 1 Executive Committee Meeting—Potential Positions of NACDS to Address Opioid Abuse

PLAINTIFFS TRIAL EXHIBIT
P-08442_00001

On Monday, May 22, I sent you a pre-read document entitled, "Potential Positions of NACDS to Address Opioid Abuse." As I stated, the May 22 document was an interim draft ahead of the NACDS Policy Council's Thursday, May 25 meeting at which they discussed suggested changes to the document for the Executive Committee to consider.

Attached you will find a red-lined version of the document which reflects the Policy Council's proposed changes to the document.

Please review this document before the June 1 Executive Committee call and be prepared to discuss it.

Please keep this document confidential and don't distribute it.

Thank you, and please let me know if you have any questions.

Steve

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Potential Positions of NACDS to Address Opioid Abuse - Pre-read

What we heard

At its April 2017 meeting, the NACDS Executive Committee directed the staff to identify additional opportunities for pharmacy to demonstrate its commitment to leadership on opioid issues. The industry already is highly engaged as a working partner to simultaneously address addiction, abuse, and access topics related to opioids. The new goal was to develop for consideration new and actionable items, including bold and comprehensive policies that NACDS potentially could support.

What we did

To accomplish this, the NACDS staff worked collaboratively to create an array of policy options across four key areas: a) broader patient pain treatment and addiction issues; b) national system reforms and technology solutions; c) pharmacy topics; and d) prescriber topics. The NACDS Policy Council is reviewing and discussing these policy options in preparation for the Executive Committee's consideration. This document (attached) describes these options, as well as a few preliminary recommendations that emerged from the Policy Council. A document containing final recommendations will be sent to you after the Policy Council's call this Thursday.

What is next

In addition to considering the policy options, NACDS will need to determine the appropriate use of this document to advance the objective: demonstrating pharmacy's existing and new efforts to provide leadership on a highly complex problem. These concepts, and their communications, fit well with the NACDS Future Value Targeting Initiative and its vision to confront pressing societal issues from pharmacy's mantle of leadership, in collaboration with other stakeholders.

A critical question for the Executive Committee is whether NACDS should take a bold response to this issue. If so, the Executive Committee can determine the breadth and extent of NACDS' engagement on this matter and align potential policy positions accordingly. Potential uses of these policy options could range from a "soft launch" approach (which would involve communications targeted to key audiences but without substantial engagement and publicity), to a highly visible, engaged strategy (which would involve earned and paid media, event-based publicity, and third-party validation).

Various options exist across this spectrum of communications possibilities. Whatever the course of action, it would seem to make strategic sense to emphasize the complexity of addiction, abuse, and access topics – and thus the need for comprehensive solutions; to position as spokespeople pharmacists and other professionals from diverse pharmacies – national and regional alike; and to emphasize that the new policy options complement existing and highly extensive efforts on behalf of pharmacies.

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POTENTIAL POSITIONS OF NACDS TO ADDRESS OPIOID ABUSE

Overriding Principles:

- **National response** to the crisis needs a unified, comprehensive national strategy that supersedes state patchwork of laws/policies.
- **Addiction** needs a compassionate response and societal acceptance (e.g., similar to mental health).
- **Chronic Pain** should be defined as a clinical disorder; millions of chronic pain patients across America should have access to appropriate pain medications to enhance their quality of life and wellbeing.
- Maintain access to opioids for patients with legitimate medical needs.
  Note: Policy Council recommends adding a new principle to ensure adequate access for patients with legitimate medical needs.

A. Broader Patient Pain Treatment / Prevention & Addiction Solutions

- **Seven-day supply limit on initial** opioid~~controlled substance~~ **prescriptions for acute pain at the federal** level that would preempt a patchwork of~~and~~ **state** requirements~~level~~**.**
  - ~~At~~ At the federal level, support Sen. Gillibrand legislation requiring prescribers to certify through the DEA registration process that they will comply with a seven-day supply prescribing limit on schedule II, III and IV opioid prescriptions issued for the initial treatment of acute pain so long as~~on the condition~~ that the legislation is amended to address pharmacy liability concerns and to preempt a patchwork of ~~.~~
  - ~~At the~~ state requirements.

    Note: Policy Council recommends edits to limit the provision to opioid prescriptions, stress the need for federal preemption to a patchwork of state requirements, and to recognize existing policy that pharmacists should not be required to enforce the limit.

- **Health plan design reforms that are designed to reduce needless opioid use and mandate treatment program coverage**.

  At the state level, pursue legislation that would:
  - Establish reduced or prorated copays for shortened day supply; serves to eliminate financial incentives for patients to obtain greater supplies of their medications;
  - Mandate that insurance medical benefit include incentives for~~insurers incent~~ e-prescribing of controlled substances;
  - Implement chronic pain management and substance abuse treatment programs and mandate coverage of these programs and treatment(s), which include: all forms of rescue medications~~,~~ along with addressing patient access barriers to complementary / alternative therapies such as physical therapy, massage,

acupuncture, etc. to provide patients with non-opioid options for dealing with their pain; and
- Ensure that provider reimbursement policies do not encourage prescribing or dispensing greater day supply (e.g. pharmacy dispensing fees should be paid each time a prescription is filled, and should not be prorated).

Note: Policy Council recommends edits to clarify that fiscal incentives should be designed within the medical benefit to target prescribers.

- **Pursue state legislation to require all payors to use an opioid management program for chronic pain patients (with appropriate exceptions for patients with pain being treated as a part of cancer care, hospice and/or patients that have are under a chronic pain treatment care plan)** with the following components:
  - a comprehensive treatment plan between doctor and patient that outlines the expectations of both parties and considers non-narcotic treatment options; pharmacists should be able to access the treatment plan;
  - a clinical risk evaluation for addiction that is signed by the patient;
  - ~~choosing a single pharmacy or pharmacy chain to be used for all opioid prescriptions; and~~
  - coverage of abuse deterrent opioid prescriptions and
  - ~~a prior authorization requirement for all new long-acting opioid prescriptions.~~

Note: Policy Council recommends that pharmacists be able to access the treatment plan and add a bullet to incentivize the use of abuse deterrent formulations.

Note: Policy Council recommends against pursuing: (1) a requirement of prior authorization for all new long-acting opioid prescriptions, and (2) lock-in programs - because a national PDMP is the preferred approach for identifying and managing high risk patients.

- **Pursue state legislation to require all payors to provide Substance Use Disorders (SUDs) Treatment Programs for opioids, heroin, cocaine et al** with the following components:
  - Mandate coverage and access to medications for SUDs and addictions as well as place all forms of rescue therapy (naloxone) on preferred drug lists; Moreover, rescue therapy should be available at the lowest cost to patients;
  - Incentivize screenings for SUDs at the physician and community pharmacy levels;
  - Require a comprehensive treatment plan between doctor, community pharmacist, and patient that outlines the expectations of treatment plan;
  - Recognize and reimburse~~Authorize~~ pharmacists to be authorized methadone monitors; administer injectable treatments; ~~be~~ providers of appropriate screenings such as HIV and Hepatitis C and requisite immunizations, allow participation; ~~participate~~ in needle exchange programs; become first responders in terms of rescue therapy; provide assistance with chronic pain care management; and deliver advance chronic disease state management for co-morbidities which includes adjusting medications, authorizing labs and prescription refills at a minimum; ~~and~~

- Authorize case workers, behavioral counselors~~,~~ and pharmacy technicians to be educated and trained in SUDs and corresponding treatment and to assist in providing~~provide~~ advanced care ~~assistance~~ in the delivery of community health care~~healthcare~~ by health departments and community pharmacies;
- Incentivize training of patients and/or family members to recognize the signs and symptoms of opioid overdose, and on the proper use of and administration of opioid antagonists to individuals actively overdosing on an opioid.
- There should be mandatory methadone coverage for private/public payers for reimbursement to pharmacies.

Note: Policy Council recommends adding last bullet to incentivize family overdose training.

Note: Policy Council recommends clarifying that pharmacists should be reimbursed for these services, and that pharmacists may be allowed to participate in needle exchange programs. There should be mandatory methadone coverage for private/public payers for reimbursement to pharmacies; and rescue therapy should be available at the lowest cost to patients. Also, a clarification that technicians may assist in providing advanced care.

- **Address broader social determinants that perpetuate addiction issues and advance funding for robust community opioid abuse/treatment and prevention programs that coordinates acute, chronic and preventive care on the front lines in neighborhoods across the country.**
  - Remove the stigma of addiction and emphasize treatment & wellness;
  - Promote culture of health programs which take into account transportation, education, and housing; among other critical factors; and
  - Identify high risk patients and engage in prevention efforts; and leverage the role of the community in addressing social determinants~~,~~ along with the medical treatment and behavioral counseling to successfully help and manage patients who are suffering from an addiction disorder by connecting care within community resources (e.g., public health departments and programs, case workers, methadone clinics, community pharmacies~~,~~ et al).
  - Support greater funding for addiction counseling/rehabilitation services and for medication assisted treatment (MAT) programs.

Note: Policy Council recommends adding in funding for MAT programs.

- **Pursue federal legislation to require all public programs and private plans to provide financial incentives to physicians and community pharmacy to identify, prevent~~,~~ and treat abuse with the following components:**
  - Incentivize screenings and treatments for SUDs at the physician and community pharmacy levels;
  - Incentivize requisite screenings and immunizations;
  - Mandate insurer coverage and access to medications for SUDs as well as place all forms of rescue therapy (naloxone) on preferred drug lists at lowest cost level to patients.

Note: Policy Council recommends that rescue therapy should be available at the lowest cost to patients.

- **Establish Accepted, Advanced National Guidelines on: "Chronic Pain Management" & "Co-prescribing of Opioids & Naloxone;" and "Co-Prescribing of Opioids."**

- **Work with state public health departments to establish state protocols that are triggered in time of declared state emergencies that expand community care by interventions provided by community pharmacies.**
  Such pharmacy care could be as first responders; screeners for hepatitis C, HIV, TB and other conditions; immunizers for a suite of vaccinations; authorized healthcare providers for methadone monitoring; provide assistance with chronic pain care management; and deliver chronic disease state management for co-morbidities et al.

B. National System Reforms and Technology Solutions

- **Agency Consolidation Concept**
  Rationale:
  The current opioid strategy is woefully inefficient in addressing the complex, multifaceted opioid epidemic crisis. Absent a comprehensive national response strategy that is implemented by one federal agency, the nation runs the risk of continuing to expend funds for continued fragmented federal and state efforts without turning the tide on this crisis.

  Action:
  The President should call for the establishment of a Department of National Drug Control, Treatment, and Prevention. This initiative would require consolidating of a vast number of federal agencies and offices responsibility for the prevention and treatment of legal and illegal drug abuse to swiftly and thoughtfully respond to the nation's opioid epidemic crisis. The President would establish a plan that builds on the recommendations of various federal agencies, national commissions, and state initiatives to develop a comprehensive national response (federal, state, and community levels).

  Seven core principles set forth below would reduce redundancy in how Congress, federal agencies, and states address this opioid epidemic crisis and maximize the efficiency of scarce government resources. It also would avoid fragmentation and overlapping efforts (and turf battles) that too often undermine the implementation of a national response strategy. To ensure that the new department has the greatest possible chance for success, Congress and the White House should ensure that the founding legislation is based on seven core principles. Specifically, the new department must:

  1. Consolidate federal offices and resources, streamlining programs and initiatives without adding any additional bureaucracy.
  2. Coordinate the policies of federal agencies and state programs with respect to substance abuse, treatment, or prevention responsibilities.

3. Develop a national framework that (1) aligns federal and state policies, business, and technology, and (2) assesses medical, scientific research, clinical practices, current and future technology, ongoing prevention, and treatment programs to develop precise initiatives.
4. Establish a national health IT structure to provide a national drug data base, and allow public and commercial entities to employ the data base to develop proactive clinical, prescribing, and dispensing tools for stakeholders as well as foster information-sharing.
5. Establish pharmaceutical manufacturer incentives for new active moiety painkillers and abuse-deterrent formulations for opioids, mandate federal and state public programs to incent e-prescribing of controlled substances; execute risk-management programs; and establish mandatory chronic pain management and substance abuse disorder education requirements in medical and pharmacy schools and beyond.
6. Integrate coverage and treatment for substance use disorders into value-based healthcare models, supporting all forms of recovery and making prevention a core health and community health measure.
7. Break the cycle of drug use, crime, and incarceration; disrupt domestic drug trafficking and production; and strengthen international partnerships.

The new federal agency would be authorized to develop and execute a highly focused national strategic response to address this crisis and to prevent further substance abuse in neighborhoods across the country. Without this action, the nation cannot be assured that its limited health, education, and enforcement resources are being effectively used to provide a unified national response to this crisis.

Establishment of Innovative National PDMP System.

- Establish one system that sets forth unified expectations of appropriate use that affect parties in healthcare and the supply chain (e.g., prescribers, insurers, manufacturers, wholesalers, pharmacies, and consumers), law enforcement, and other legitimate users of PDMP data.
- The PDMP system should be free-of-charge to users
- Standardization for data collection, analyses, outcomes, and evaluation, through data that comes from e-prescribing.~~.~~
- Proactive timely, in-workflow~~analyses on real-time data with actionable point-of-care~~ guidance for the prescriber and dispenser, including identifying those addicted for treatment and preventing others from suffering from addiction
- Reduction of fraudulent prescribing; and maximize clinical outcomes, patient safety, and system security.

Note: Policy Council recommends that a national PDMP should be free-of-charge to users; clarify that data should come from e-prescribing and the PDMP should provide timely, in-workflow guidance to the prescriber and dispenser.

- **Mandatory system e-prescribing, and especially for every medication that must be reported to a PDMP.**

- Reduce the likelihood of fraudulent prescribing and add new dimensions of safety and security to the process; NACDS will work at the state level to enact legislation requiring that prescriptions be electronically transmitted.
- Support the draft Clark/Bilirakis bill that would establish mandatory e-prescribing of all schedule II-V opioid prescriptions as a condition of Medicare Part D Coverage on the condition that the legislation is amended to address coverage issues and pharmacy liability concerns.

- **Establish a Coalition to Enhance Patient Safety and Curb Prescription Drug Abuse**
  - Goals of the coalition would be to:
    - Secure bipartisan support for mandatory e-prescribing at the federal and state levels; and
    - Garner support for a national PDMP solution.

  - Coalition would bring together diverse organizations/entities to influence e-prescribing federal and state policies and the establishment of a national PDMP system to advance:
    - Patient safety by reducing medication errors.
    - Patient health by having providers having access to actionable and complete patient data.
    - Community health by curbing prescription drug abuse.
    - State agencies, AGs and other local ~~L~~law enforcement efforts by central data base.
    - Commercial efficiencies across the healthcare continuum.

    Note: The Policy Council recommends clarifying the breadth of the coalition; and a comment that national PDMP should include a bifurcation of law enforcement and clinical use to avoid prescribers and pharmacists "policing" patients.

- **Support swift implementation of The Ensuring Patient Access and Effective Drug Enforcement Act of 2016.**
  This enacted bill requires DEA and various agencies under HHS to coordinate on a report to Congress that identifies obstacles to legitimate patient access to controlled substances and how collaboration among federal and state agencies and industry can benefit patients and prevent diversion and abuse of controlled substances. The report to Congress is now past due.

- **Establish incentives to foster pharmaceutical research on innovative abuse-deterrent formulations (ADFs) of opioids, novel nonaddictive painkillers (e.g., products that contain novel active moieties); and family/friend friendly rescue treatments (e.g. user to use naloxone) which will yield tremendous societal benefits.**
  - Offer a number of incentives to pharmaceutical companies that develop non-addictive pain products, and ~~establish a centralized system~~ to ~~coordinate and~~ facilitate the development process of those drugs. Incentives could include among other things:

- (1) a tax credit equal to 50% of the development costs attributable to qualified clinical testing in addition to the traditional research tax credit for pharmaceutical manufacturers;
- (2) priority review status for such drug products by FDA which shortens the average review period to 6 months;
- (3) 10 years of market exclusivity for a product containing a novel active moiety that is a nonaddictive painkiller; and 7 years of market exclusivity for a product that employs an abuse-proof version of FDA approved opioid product; and
- (4) seven-year patent extension for one patent that directly covers the type of products set forth in (3) above.

Note: Policy Council recommends removing mention of a central database. As to points (3) and (4), an economic analysis may be necessary to determine the precise number of years of market exclusivity et al.

- **Pursue legislation for state PDMPs reforms.**
  While a national PDMP is being established, work at the state level to support legislation and regulations that would:
  - Establish requirements for dispensers to report controlled substance dispensing information to state PDMPs on a daily basis, especially if 7 day supply limits for initial fills of controlled substances are enacted (Notably, 34 states have enacted a daily reporting requirement);
  - Require standardization of data to improve the usefulness of PDMP information;
  - ~~Require prescribers of controlled substances to check state PDMP prior to prescribing controlled substances (Notably, 36 states have enacted requirements for mandatory prescriber PDMP use);~~
  - ***Support the American Medical Association (AMA) recommendation for prescriber use of PDMPs. NACDS further supports allowing for technology solutions that enable prescribers to access PDMP information in-workflow.***
  - ~~Require pharmacists to check state PDMP prior to dispensing controlled substances when one or more red flags are present (7 states have enacted requirements for pharmacists to check the PDMP in limited, specified circumstances).~~

  Note: Policy Council recommends replacing the original language of bullet three with supporting AMA's policy. The Policy Council recommends deleting bullet four due to its belief that state laws should allow pharmacists to check the PDMP pursuant to their professional judgment.

C. Pharmacies

- ~~Pursue federal and state pharmacy lock-in programs that would require "high-risk chronic pain" patients to select one pharmacy or pharmacy chain to fill their opioid prescriptions.~~
  - ~~Encourage CMS to implement the Medicare Part D lock-in program.~~
  - ~~Pursue state Medicaid lock-in programs.~~
  - ~~Pursue efforts to require commercial payors to implement lock-in programs.~~

  Note: Policy Council recommends opposing the pursuit of lock-in programs since a national PDMP is the preferred approach for identifying and managing high risk patients.

- **Manufacturer paid-for return envelope** available upon request to any patient to whom an **opioid prescription** is dispensed**.**
  - ~~Pursue state legislation requiring that opioid manufacturers pay for a return envelope for drug disposal purposes that pharmacies would provide with every opioid prescription dispensed.~~

Note: Policy Council recommends editing to limit this initiative as follows –"Manufacturer paid-for return envelope available upon request to any patient to whom an opioid prescription is dispensed." The rationale is that Policy Council expressed concern with chain pharmacy recommendations mandating policy for manufacturers.

- **Manufacturer paid-for prevention counseling at the point of dispensing in community pharmacies and health departments for every patient being dispensed an opioid prescription to prevent addiction and educate on SUDs, and that also addresses security and proper disposal of unused medications.**

- **Mandatory continuing pharmacy education for pharmacists and pharmacy school education on pain management and safe opioid use.**
  - Work at the state level to enact a regulation that would require all pharmacists to complete ongoing continuing pharmacy education programs on pain management or safe opioid use and/or medication assistance treatment. ~~and safe opioid use.~~
  - Encourage pharmacy schools to incorporate mandatory coursework on pain management and safe opioid use into the curriculum.

Note: The Policy Council recommends editing to provide more options for continuing pharmacy education.

- Mandatory manufacturer drug assistance programs for naloxone available to patients and/or family members who are not otherwise able to afford this costly medication.

Note: Policy Council recommends adding a bullet on mandatory manufacturer drug assistance programs for naloxone to patients and family members unable to afford it.

D. Prescribers

- **Mandatory continuing medical education and medical school education programs on pain management and safe opioid use for physicians and other healthcare providers who prescribe controlled substances.**
  - Encourage medical schools to incorporate mandatory coursework on pain management and safe opioid use into the medical school curriculum.
  - Encourage medical schools to incorporate~~Establish~~ a three-year pain medicine residency program as chronic pain should be recognized as a clinical disorder
  - Work at the state level to require physicians and other healthcare providers who prescribe controlled substances to complete ongoing continuing education on pain management and safe opioid use.

Note: Policy Council recommends editing this bullet to encourage medical schools to do this, not require.

- **Mandate that the state's Medical Licensing Board must complete an annual assessment of prescribers and opioid prescriptions to identify over-prescribers of opioids and inappropriate actions and take the corresponding enforcement and regulatory actions.**
    - A small percent of the prescribing physicians are often responsible for a considerable number of opioid prescriptions.

  ***Note:** The Policy Council debated whether promoting this would open pharmacy up to similar recommendations by the medical community and whether chain pharmacy should be the voice to suggest this. Yet, they recognized the potential value of a profession self-policing profession and AMA might support the concept.*

- **CDC Guidelines for Prescribing Opioids for Chronic Pain**
    - Communicate our support.

- **Co-prescribing of naloxone and opioids**
    - ~~Pursue state legislation to require all polydrug use of opioid and benzodiazepine prescriptions, and other potentially fatal combinations, to be accompanied by a naloxone prescription.~~ Authorize pharmacists to prescribe and dispense naloxone immediately upon identifying potential substance abuse by a patient taking an opioid prescription, or an individual that presents with possible abuse of heroin. Mandate plan coverage of rescue therapy provided by pharmacists.

  ***Note:** Policy Council recommends deleting a mandate that all opioid prescriptions be co-prescribed with naloxone, and include a requirement for plan coverage of rescue therapy provided by pharmacists.*